



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

September 1, 1999

Jonathan W. Emord, Esq.
Emord & Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

RE: Health Claim Petitions: "Petition for Health Claim: Folic Acid, Vitamin B₆, and Vitamin B₁₂ Dietary Supplements and Vascular Disease" and "Petition for Health Claim: - Saw Palmetto and Benign Prostatic Hyperplasia"

Dear Mr. Emord:

This is in reference to the health claim petitions that you submitted on behalf of Julian M. Whitaker, MD; Durk Pearson and Sandy Shaw; American Preventive Medical Association; and Pure Encapsulations, Inc., on May 25, 1999 to the Food and Drug Administration. In accordance with section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act, we will be filing these petitions. At the time of filing, health claim petitions are placed in a public docket and become available for public review. However, the filing of a health claim petition does not indicate that the agency has completed its review nor determined whether all preliminary requirements for the petition have been satisfied. FDA is required to make a decision about whether to issue a proposed regulation within 90 days of the filing date and, therefore, will be conducting further review of the information in your petitions.

Please feel free to contact me at the above address or call me at 202-205-4500 if you have any questions.

Sincerely,

Susan M. Pilch, Ph.D.
Team Leader - Nutrition, Health Claims, and Dietary Supplements
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

cc:
GCF-1 (Overholser)
HFS-450 (Yetley)
HFS-451 (Lewis)

99P-3029

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